

Docket No.: AJC 201.1 US/10304772

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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DEC 23 2003

In re Provisional Application of:
Joseph Artiss, et al.

Application No.: 10/628,475

TECHNOLOGY CENTER R3700

Filed: July 29, 2003

Art Unit: 3765

For: COMPOSITIONS COMPRISING DIETARY
FAT COMPLEXER AND METHODS FOR
THEIR USE

Examiner: Not Yet Assigned

FIRST INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

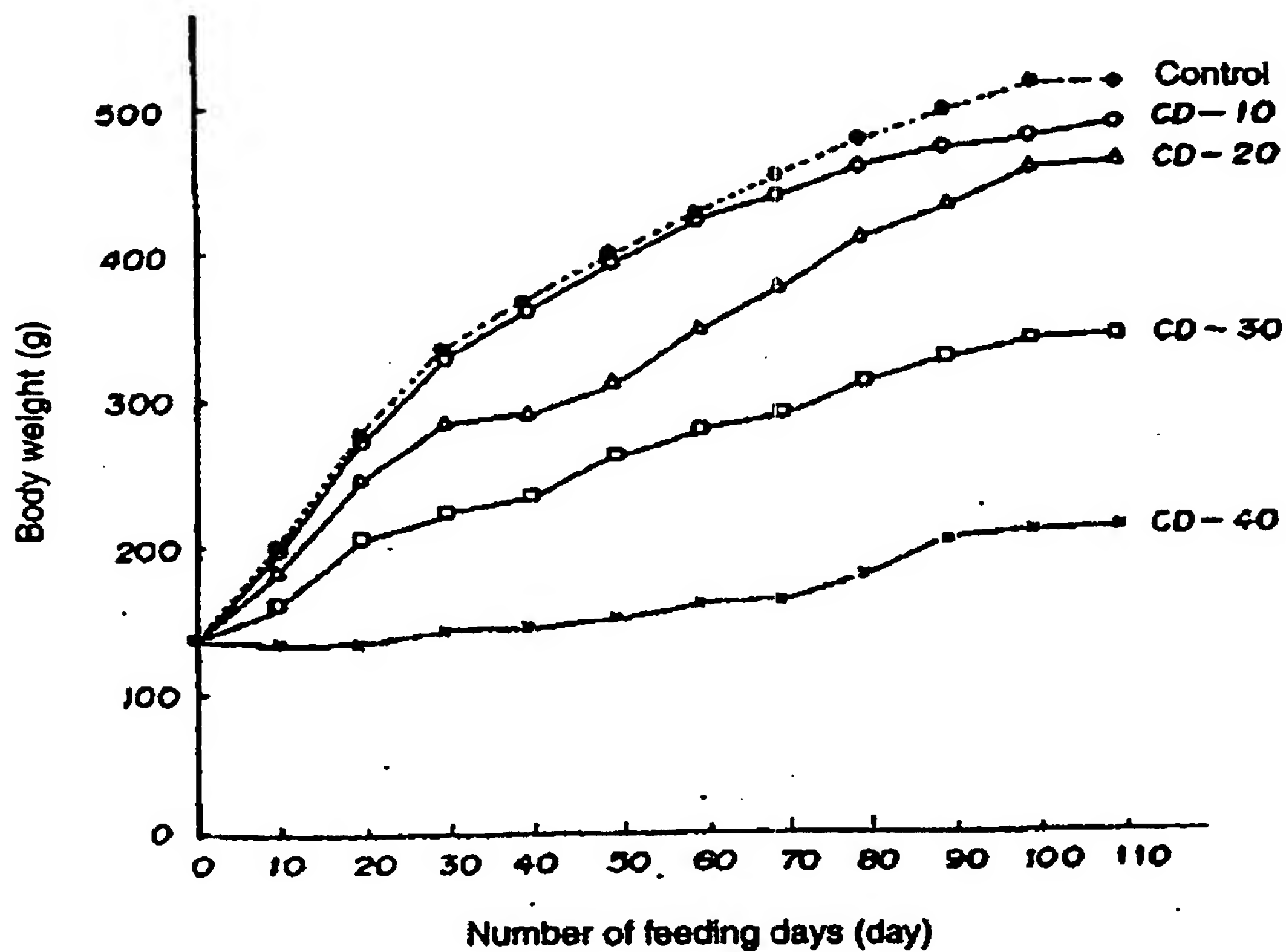
Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

The Examiner's attention is directed to the Japanese reference Unexamined Patent Application S60-94912 (Inventor Suzuki et al.) and particularly to page 7 lines 3-5 of the English translation provided herewith, which recites:

"To achieve the objective of the present invention, α -cyclodextrin (and α -cyclodextrin for the composition with α -cyclodextrin as the major component) should be used at 10% or more. For body weight suppression and body weight reduction, preferably it should be used at 20% or more, even more preferably used in the range of 20-30%."

The reference also includes the following graph, Figure 5:

Fig. 5



In addition the journal article "Nutritional Significance of Cyclodextrins: Indigestibility and Hypolipemic Effect of α -Cyclodextrin", *J. Nutr. Sci. Vitaminol.*, 31:209-223 (1985) by Masahige Suzuki and Atsuko Sato (Masahige Suzuki is first named inventor on the Japanese application) has many of the same figures, particularly Figure 4,

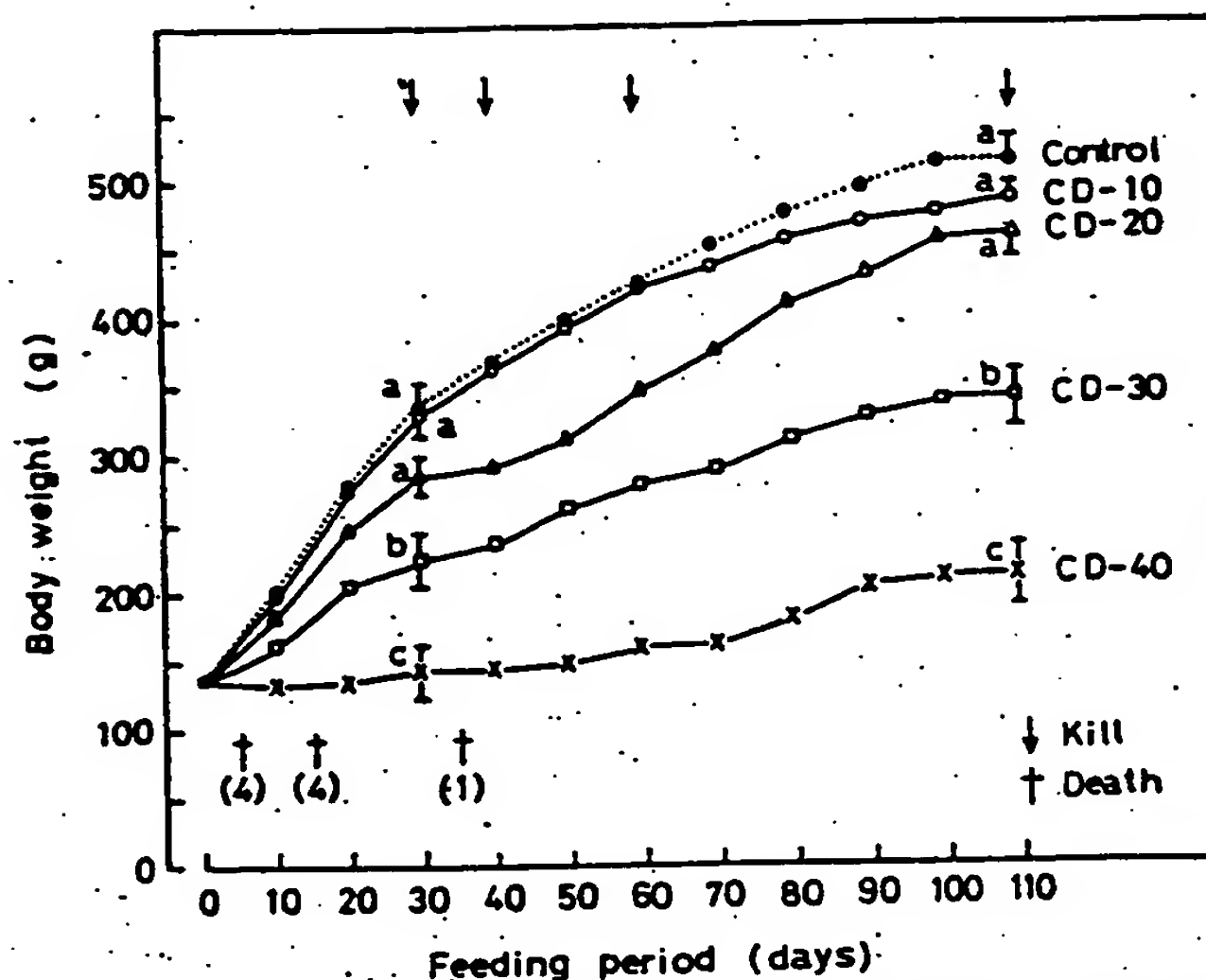


Fig. 4. Changes in weight gain of rats during a 110-day period of meal-feeding of CD diets (Exp. 4). Number in parentheses are rats of the CD-40 group which died during each 10-day period. Each point and vertical line respectively represents means and SEM for 5-20 rats. Values not followed by the same letter are significantly different ($p < 0.05$).

which is Figure 5 in the Japanese application. The journal article states "A significant difference in weight gain was observed between the control and CD-30 and 40 groups ($p < 0.05$)."

(page 215, 2d full sentence). The CD-30 and CD-40 diets contain a total of 18% and 24% α -cyclodextrin respectively. The legend of Figure 4 in the Suzuki and Sato journal article states "Values not followed by the same letter are significantly different ($p < 0.05$)". The control, CD-10 (6% α -cyclodextrin) and CD-20 (12% α -cyclodextrin) are all followed by an "a" demonstrating that the body weight gain in rats fed the CD-10 and CD-20 diets were NOT significantly different from the control.

In drafting the application the undersigned relied on a combination of the references as the basis for the statement:

“If the α -cyclodextrin is less than 20% of the total dietary intake, S60-094912 reports that there is no significant difference in weight loss as compared to a control diet.” (Page 10, lines 23-25)

The undersigned now understands that the statement on page 10, lines 23-25 of this application might be construed as being inconsistent with these Japanese references. In the event that the statement is inconsistent with the references, such inconsistency was unintentional and applicants' representative along with applicants take this opportunity to provide the underlying material for evaluation by the Examiner. In addition a preliminary amendment is filed herewith deleting the above-referenced sentence (page 10, lines 23-25).


This Information Disclosure Statement is filed prior to the first Office Action in the application.

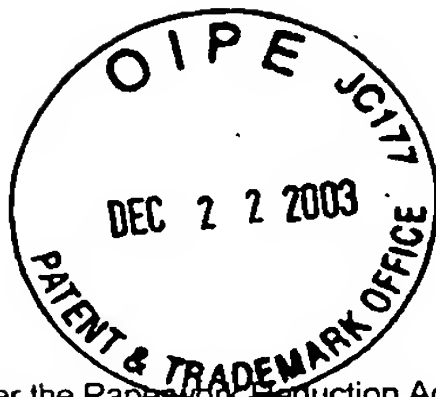
A copy of each non-U.S. Patent reference on PTO/SB/08 is attached.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 06-2375, under Order No. AJC 201.1 US/10304772. A duplicate copy of this paper is enclosed.

Dated: Dec. 22, 2003

Respectfully submitted,

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PTO/SB/08A (10-01)
Approved for use through 10/31/2002 OMB 0651-0031
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO				Complete known Technology Center R3700	
				Application Number	10/628,475
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Filing Date	July 29, 2003
				First Named Inventor	Joseph Artiss, et al.
				Art Unit	3765
				Examiner Name	Not Yet Assigned
Sheet	1	of	1	Attorney Docket Number	AJC 201.1 US

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA	US-4,880,573	11-14-89	Courregelongue et al.	
	AB	US-5,189,149	02-23-93	Bruzzese et al.	
	AC	US-5,232,725	08-03-93	Roderbourg et al.	
	AD	US-5,560,950	10-01-96	Conte et al.	
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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	BA	JP 05164024	12-12-94	DR MAINTSU:KK		
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	BI	JP 52010448	01-26-77	RIBBON SHOKUHHIN KK, et al.		
	BJ	EP 1 120 046 A1	01-08-01	NIHON SHOKUHHIN KAKO CO., LTD		
	BK	JP 60-049752	03-19-85	SANYUU SHOJI KK		
	BL	JP 2-261334	10-24-90	KANEGAFUCHI CHEM IND CO LTD		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

¹ Applicant's unique citation designation number (optional). ² See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Sheet	2	of	1		

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²	
	CA	G. H. ANDERSON, et al., "The Utilization of Schardinger Dextrins by the Rat", Toxicology and Applied Pharmacology, 1963, pgs. 257-266		
	CB	KAZUKO SHIMADA, et al., "Structure of Inclusion Complexes of Cyclodextrins with Triglyceride at Vegetable Oil/Water Interface", Journal of Food Science, Vol. 7, 1992, pgs. 655-656		
	CC	MASASHIGE SUZUKI, et al., "Nutritional Significance of Cyclodextrins: Indigestibility and Hypolipemic Effect of α -Cyclodextrin", J. Nutr. Sci. Vitaminol. 31, 1985, 209-223		
	CD	SARUNYA KAEWPRASERT, et al., "Nutritional Effects of Cyclodextrins on Liver and Serum Lipids and Cecal Organic Acids in Rats", J. Nutr. Sci. Vitaminol. 47, pgs. 335-339		
	CE	JOZSEF SZEJTLI, "Utilization of Cyclodextrins in Industrial Products and Processes", J. Mater. Chem., 1997, pgs. 575-587		
	CF	CATHERINE JEN, PH.D, et al., "Lipid Lowering Effect of Omega-3 Fatty Acids in Genetically Obese Zucker Rats", Nutrition Research, Vol. 9, 1989. pgs. 1217-1228		
	CG	RYOZO TAKADA, et al. "Dietary γ -Linolenic Acid-Enriched Oil Reduces Body Fat Content and Induces Liver Enzyme Activities relating to Fatty Acid β -Oxidation in Rats", American Institute of Nutrition, November 15, 1993		
	CH	RABEN, et al., "Acetylation of or Beta-Cyclodextrin Addition to Potato Starch Beneficial Effect on Glucose Metabolism and Appetite Sensations", Am J Clin Nutr, 66(2): 304-14, 1997.		
	CI	YUAN, et al., "Application of Molecular Encapsulation for Toxicology Studies: Toxicokinetics of p-chloro-alpha, alpha, alpha-trifluorotoluene in alpha-cyclodextrin or corn oil vehicles in male F344 rats, Toxicol Appl Pharmacol. 111(1): 107-15, 1991		

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